

Structured Product Labeling (SPL) OTC Sub-team Teleconference

June 15, 2009, 1:00 – 2:00 pm ET

Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Joan Berger, Image Solutions, Inc.
-  John Blasofsky, Glemser Technologies Corporation
-  Cheryl Blik, Teva Pharmaceuticals USA
-  David Brown, Colgate-Palmolive
-  Shelia Dy Juanco, Medline Industries, Inc.
-  Chris Guay, The Procter & Gamble Company
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team co-leader)
-  Devon Morgan, Perrigo Company (sub-team co-leader)
-  Priscilla Mott, Johnson & Johnson Consumer & Personal Products Worldwide
-  Jeff Poisson, i4i
-  Alison Rago, Intagras
-  Janet Riffitts, McNeil Consumer Healthcare
-  Eva Rivera, Glemser Technologies Corporation
-  Gary Saner, Reed Technology and Information Services, Inc.
-  David Schilling, Chattem, Inc.
-  Howard Shatz, Data Conversion Laboratories, Inc.

-  Siobhan Stevens-Miles, Merck & Co., Inc.
-  Carl Strotz, Wyeth Consumer Healthcare
-  Beth Thompson, Medline Industries, Inc.
-  Craig Trautman, Intagras
-  Ranga Velagaleti, BASF, Inc.
-  Karen Vescovi, Church & Dwight Co., Inc.
-  Ann Vu, FDA
-  Barbara Wolfe, Wyeth Consumer Healthcare
-  Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: June 29, 2009 (unless cancelled)

III. FDA [Guidance for Industry](#) - Final

The final guidance was released on May 29th. It was noted that FDA intends to make arrangements to obtain DUNS numbers for entities that do not provide them to the agency.

IV. Highlights from Second FDA Face-2-Face Meeting

Highlights from the June 10th meeting were reviewed in addition to being provided as a separate document.

V. Discussion Topics

A. Terminology – “Box” vs. “Carton”

There appears to be a difference between the agency and industry in interpretation of “box” vs. “carton.” Many in industry consider the outer package that holds the bottle, blister pack, etc. to be the “carton” which is

then placed into a corrugated (*e.g.*, “shipping”) “box.” But the agency seems to interpret the outer package holding the bottle to be the “box” which is then placed into a “carton.” Clarification will be sought as this could potential affect how information is listed in the SPL submissions (*e.g.*, one bottle in box vs. carton).

B. OTC Drug Listing Information

On several different occasions the question has arisen about whether or not OTC Drug Listing information will be posted to the National Library of Medicine (NLM) DailyMed website (or similar site within the FDA). Agency staff is currently discussing the issues. SPL OTC sub-team members are asked to have internal discussions about why or why not to post the OTC drug listing information to the public domain. Points to consider include:

- Potential risks/benefits or pros/cons of posting information to the public domain
- Necessary safeguards if made publicly available
- Other considerations/concerns

If there are key elements or points of agreement amongst the sub-team members for a recommended approach, a letter outlining these considerations will be submitted to FDA for their review (assuming that is the determined course of action). Although not guaranteed, FDA may consider the recommendations. Additional discussion will occur during future sub-team calls but the sooner a decision is reached, the quicker the information could be sent to the agency.

Feedback can be given to sub-team co-leaders Paula Markert (GSK) and Devon Morgan (Perrigo), and Marcia Howard (CHPA) via email. You may also send the information to Marcia only if you would prefer to remain anonymous.

VI. FDA Data Council

- A. The new FDA Data Standards Council website was launched on Friday, May 29, 2009

<http://www.fda.gov/ForIndustry/DataStandards/default.htm>

- B. Updates – May not be all inclusive

1. UNII's: Note: The term UNII (not UNII code) is the correct name.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM164486.zip>

2. Added update UNII XML file to XML terminology

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM164095.zip>

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM164474.zip>

3. Updated counter-ion validation file

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM164098.zip>

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM164479.zip>

4. Updated Documents

- a. Stability data schema
- b. Implementation Guide
- c. Input Tool Requirements





The three aforementioned documents are accessible via this web page:

<http://www.fda.gov/ForIndustry/DataStandards/StabilityDataStandard/default.htm>

5. The following documents were removed from the SPL Resources web page:

- a. SPL Release Three Implementation Guide (Relocated to SPL IG archive)
- b. Electronic Labeling Information Processing System (ELIPS) Validation and Conformance Rules (Removed)

VII. Open Discussion by Sub-team Members

-  John Blasofsky (Glemser) commented that as soon as FDA gets the electronic submission it considers the establishment as being registered but it may take longer (possibly up to several months) to get the FEI number back.
-  It was suggested that the “unapproved other category” be used for ingredients that may not be covered under a specific OTC monograph.
-  It seems that electronic submissions such as the NDC Labeler Code and registrations will be processed nearly instantaneously, so they should not be delayed like FEI number processing.
-  FDA held its second Q&A session today (see below). Highlights from the call include.
 - The marketing date entered informs FDA when the information can be released publicly but allows the drug listing staff to have access to the content prior to posting. The marketing date should also assist companies with appropriate handling of imported products that have not yet entered the U.S. marketplace.
 - Codes and symbols within imprints are not recognized by the SPL system. Semi-colons should be used to designate spaces, decimal points, etc. For example, 2.5 mg would be represented in the SPL document as 2;5 or ½ would be represented as 1;2.
 - FDA is considering a “no change” document for drug listing but no final decisions have been made.

- Under SPL R4, the revised date is now under the control of the individual companies. With SPL R3, it was the date when FDA received the file.
- It is up to each individual company to determine what it believes is a “representative label.”
- Once an R4 drug listing submission has been completed, if there is a change to the package, a new NDC will be required.
- Establishment data is not needed for products that are no longer marketed or discontinued.
- FDA will give priority review status to actual submissions (if there are validation errors or questions/issues) compared to test submissions.
- Companies should complete a thorough review of the SPL documents prior to submission to maximize accuracy of the information. However if there is a simple mistake (*e.g.*, a minor typo) you can email FDA to explain the situation to determine an update is needed. This process should be used on a limited, case-by-case basis.

VIII. Upcoming SPL Educational Forums

A. FDA SPL R4 Training Session 12 (webinars) – Sessions 10 and 11 are now closed

B. FDA SPL R4 Training Sessions 14 and 15 (webinars)

- ✓ Session 14 – Preparing Bulk Ingredient/Bulk Product Electronic Drug Listing Submissions - June 19, 2009, 9:00 – 10:30 am ET
- ✓ Session 15 – Preparing OTC Drug Product Electronic Drug Listing Submissions – June 26, 2009, 9:00 – 10:30 am ET

- ✓ For details about training sessions 14 & 15 visit
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

C. FDA weekly SPL R4 Q&A/Training session

June 8, 2009 – December 28, 2009
Mondays (except June 22, 2009 & Federal holidays)
11:30 a.m. – 12:00 p.m., EST

Audio conference details:

Telephone number: 1-866-775-9435
Participant pass code: 2219058

D. DIA SPL Workshop (August 11-12, 2009, The Westin, Philadelphia, Philadelphia, PA).

Please visit <http://www.chpa-info.org/meetings/StructuredProductLabelingMeeting.aspx> for more information.

E. A training session for submitting information for kits in SPL format is expected so watch for more information.

MDH/06-17-09

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Last Revised: June 17, 2009 Sent: June 17, 2009